



Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

DATE: February 5, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: ETHEX Corporation- Expanded Prescription Recall

SUGGESTED

ACTION: Prescription Recall; Due to GMP violations; No action is required. For consumer inquiries only.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. ETHEX Corporation has expanded recall to retail level.

ETHEX Corporation Issues Voluntary Nationwide Recall *Previously Issued Recall to Wholesale Level On Certain Products Expanded to Retail Level*

Contact:

Ann McBride, ETHEX Corporation
800-748-1472

FOR IMMEDIATE RELEASE -- St. Louis, MO, February 3, 2009 – ETHEX Corporation, a subsidiary of KV Pharmaceutical Company (NYSE: KVa/KVb), is issuing a voluntary expansion to the retail level of a previously announced recall on certain products. The recall on the products listed below had previously been issued to the wholesale level, but is now being expanded to the retail level. The Company is taking this action as a precautionary measure, because the products may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practice (cGMP). This additional level of recall is to further remove recalled products from the marketplace.

Patients who may have these products in their possession should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medications may place patients at risk. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products.

Expanded Recall to Retail Level Includes the Following Products:

- Morphine Sulfate Extended-Release Tablets 15mg, 30mg & 60mg (All Strengths)
- Morphine Sulfate Immediate-Release Tablets 15mg & 30 mg (All Strengths)
- Dextroamphetamine Sulfate Tablets 5mg & 10mg (All Strengths)
- Isosorbide Mononitrate Extended-Release Tablets 30mg, 60mg & 120mg (All Strengths)

- Propafenone HCl Tablets 150mg, 225mg & 300 mg (All Strengths)

Any retail customer inquiries related to this action should be addressed to ETHEX Customer Service at 1-800-748-1472, faxed to ETHEX Customer Service at 314-646-3788, or e-mailed to customer-service@ethex.com. Representatives are available Monday through Friday, 8 am to 5 pm CST.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA). At this time, the Company is unable to determine when distribution of these products will resume.

Patients with questions about the recall should call the telephone number above, or contact their healthcare providers. Any adverse reactions experienced with the use of these products should also be reported to FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch

The recall announcement is posted on www.kvpharmaceutical.com.

#

[RSS Feed for FDA Recalls Information](#) [\[what's this?\]](#)
